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10/523,918	10/18/2005	Cecilia Lucia Clara Lelivelt	702-050119	1947

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EXAMINER
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KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

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09/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,918	<b>Applicant(s)</b> LELIVELT ET AL.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-89 is/are pending in the application.  
4a) Of the above claim(s) 67-81 and 85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24, 41-66, 82 and 86-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's election without traverse of Group I (claims 41-66, 82-84 and 86-89) in the reply filed on 12 July 2007 is acknowledged. Applicant urges that claim 85 belongs to Group I, as it is dependent upon claim 83. This is not persuasive because claim 85 is drawn to a vector, while the parent claim is drawn to a plant. Claims 67-81 and 85 are withdrawn from consideration as being drawn to a nonelected invention.

### ***Claim Objections***

2. Claims 46 and 56-57 are objected to because of the following informalities:

Claim 46 has the misspelling "proplasisds".

Claim 57 has the misspelling "transformatino".

In claim 56, line 2, --the group consisting of-- should be inserted after "from".

3. Claim 53 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Because the claim excludes two of the steps recited in parent claim 41, it does not include all of the limitations of that claim, and thus fails is broader than that claim.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 48, 50, 52-53 and 55-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 48 recites the broad recitation "therapeutic or prophylactic (bio)pharmaceutical (poly)peptide", and the claim also recites "edible vaccine" which is the narrower statement of the range/limitation. Claim 52 recites the broad recitation "visual marker", and the claim also recites "fluorescent marker" which is the narrower statement of the range/limitation.

Claim 50 is indefinite in its recitation of "wherein the terminator is selected from the group consisting of the *psb* A termination sequence, *rrn*, *rbcL*, *trnV* and *rpsl6*" as *rrn*, *rbcL*, *trnV* and *rpsl6* are entire genes, not just terminators.

Claim 55 is indefinite because the DNA segments would only be homologous to the recited portions of the lettuce plastid genome if the method were performed on lettuce of closely related plants. However, the limitation in claim 42 and all its dependent claims that the plant species is Asteraceae is not related to the source of the plant material in part b), which can be from any plant.

Claim 56 is indefinite in its recitation of "LCV1 A-B", "LCV1 C-D", "LCV2 A-B" and "LCV2 C-D". It is not clear from pg 17-19 of the specification exactly what these refer to. It is suggested that the portions of SEQ ID NO:1 to which each of these correspond be recited instead.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 41-47, 49-52, 54, 57, 61-65, 82-84 and 86-89 are rejected under 35 U.S.C. 102(b) as being anticipated by Blowers et al (WO 99/05265).

Blowers et al teach transformation of tobacco plastid genomes by transforming by particle gun transformation nonphotosynthetic tobacco suspension cells with a plasmid comprising an expression cassette comprising the Prn promoter operably linked to distronic gusA-aadA or hph-aadA or tricistronic glpB-hph-aadA operably linked to the psbA terminator and flanked on one side by petunia rps7/rsp12 and the other by trnI/trnA, placing the plant

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material for two days on medium lacking a selection agent, then transferring to medium comprising the selection agent spectinomycin or glyphosate, and maintaining the resulting calli on either solid or liquid selection media, thus, refreshing the culture medium comprising the selection agent (pg 42, line 20, to pg 44, line 22; pg 49, line 6, to pg 53, line 24; pg 54, line 1, to pg 57, line 10). The resulting transformed calli had the expression cassette inserted into the plastid genome (pg 47, lines 1-9).

The expression cassette comprises a HindIII insertion site (pg 43, lines 5-8), and the gusA coding sequence would be the gene of interest. The nonphotosynthetic tobacco suspension cells contain proplastids (pg 7, lines 2-5). GusA is a visual selection marker when the cells are grown in the correct medium. hph and glpB are genes of interest that confer resistance to the herbicide glyphosate. The limitation in claim 42 and all its dependent claims that the plant species is Asteraceae has not been given patentable weight because the recitation occurs in the preamble; the plant material used in step b) of claim 41 can be of any species. rps7/rsp12 and the other by trnI/trnA allow double homologs recombination of the DNA of interest with the plastid genome because they have a DNA sequence that is homologous to the a part of the plastid genome. As plant parts include calli and as transformed plastid containing cells were produced from those calli (pg 51, lines 16-19), progeny were produced from the plant parts.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 41-47, 49-52, 54, 57-65, 82-84 and 86-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blowers et al (WO 99/05265) in view of Maliga et al (US Patent 6,388,168).

The claims are drawn to a method of plastid transformation in which newly cells with transformed plastid are cultured for up to 6 days on media lacking a selection agent before being moved to media with a selection agent, wherein the plastids are transformed by polyethylene glycol mediated transformation.

The teachings of Blowers et al are discussed above. Blowers et al do not disclose polyethylene glycol mediated plastid transformation or placing the cells on medium lacking a selection agent for up to 6 days.

Maliga et al teach that polyethylene glycol mediated transformation is one alternative for plastid transformation (column 16, line 54, to column 17, line 10).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of plastid transformation as taught by Blowers et al, to transform the plastids by polyethylene glycol mediated transformation as described in Maliga et al. One of ordinary skill in the art would have been motivated to do so because use of one method over another is an obvious design choice. Additionally, it would be obvious to one of skill in the art to experiment with different lengths of times of exposure to the medium lacking a selection agent in the optimization of experimental protocols.

10. Claims 41-52, 54, 57, 59-65, 82-84 and 86-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blowers et al (WO 99/05265) in view of Daniell (WO99/10513).

The claims are drawn to a method of plastid transformation in which newly cells with transformed plastid are cultured for up to 6 days on media lacking a selection agent before being moved to media with a selection agent and in which the plastid are transformed with a construct encoding a therapeutic or prophylactic (bio)pharmaceutical (poly)peptide.

The teachings of Blowers et al are discussed above. Blowers et al do not disclose expression of therapeutic or prophylactic (bio)pharmaceutical (poly)peptides in the plant plastids or placing the cells on medium lacking a selection agent for up to 6 days.

Daniell teaches a method of plastid transformation of a large number of plant species (pg 40, line 29, to pg 51, line 10). Daniell et al also suggests expression of therapeutic or prophylactic (bio)pharmaceutical (poly)peptides in plant plastids (pg 14, lines 13-22; pg 31, line 9, to pg 33, line 19).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of plastid transformation as taught by Blowers et al, to express the therapeutic or prophylactic (bio)pharmaceutical (poly)peptides described in Daniell in plant plastids. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Daniell to express these proteins in plastids. Additionally, it would be obvious to one of skill in the art to experiment with different lengths of times of exposure to the medium lacking a selection agent in the optimization of experimental protocols.

11. Claim 53 is free of the prior art, given the failure of the prior art to teach or suggest a method of plastid transformation comprising culturing the transformed plastids on media lacking a selection agent before selecting transformants with a light source corresponding to a visual



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marker. Claims 55-56 are free of the prior art, given the failure of the prior art to teach or suggest a method of plastid transformation in which the plastids transformed with a construct comprising lettuce trnI (oriA)trnA or 16S/trnV/Orf70B.

12. Claims 53 and 55-56 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### *Conclusion*

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Anne Kubelik, Ph.D.  
September 20, 2007

/Anne Kubelik/  
Primary Examiner